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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/938,901 | 08/24/2001 | Seiki Kuramitsu | 11283-013001 | 5458 |

7590

09/23/2003

GREGORY P. EINHORN
Fish & Richardson P.C.
Suite 500
4350 La Jolla Village Drive
San Diego, CA 92122

EXAMINER

MARVICH, MARIA

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 09/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/938,901

Applicant(s)

KURAMITSU ET AL

Examiner

Maria B Marvich, PhD

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 4-31 and 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) is/are allowed.
- 6) ☒ Claim(s) 1-3 and 32 is/are rejected.
- 7) ☐ Claim(s) is/are objected to.
- 8) ☐ Claim(s) are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.65(a).
- 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. .
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1/2002.
- 4) ☐ Interview Summary (PTO-413) Paper No(s).
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Claims 1-35 are pending in this application. An IDS filed 5/1/03 has been received and the documents considered. The signed and initialed PTO Form 1449 has been mailed with this action.

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-3 and 32 directed to SEQ ID NO:2) in the paper filed 8/18/2003, is acknowledged. Claim 3 has been examined in so much as it reads on SEQ ID NO:1, which is the nucleotide sequence of the amino acid sequence of SEQ ID NO:2.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by White et al.

White et al disclose an amino acid sequence from *Deinococcus radiodurans* that is 39.4 percent homologous to the amino acid sequence disclosed in SEQ ID NO:2. Claims 1 and 2 recites that the isolated protein comprises/consists of an amino acid of SEQ ID NO:2. While claim 32 recites a fusion protein that is a subsequence of a first amino acid sequence. Given the percent homology between the sequence taught by White and that of SEQ ID NO: 2, the nucleotide sequence of White et al. reads on "an amino acid sequence" or "a subsequence" of the instant invention. Claim 3 recites an isolated protein encoded by a nucleic acid that hybridizes

under stringent conditions. Applicant teaches that "stringent hybridization" refers to hybridizations or wash conditions under which nucleic acid will primarily hybridize to its target subsequence (page 25, line 23-27). A part of the sequence of White et al that is homologous to a part of the sequence of the instant invention would necessarily hybridize to the sequence of the instant invention. Therefore, the nucleotide sequence of the sequence taught by White et al. would under hybridize under the conditions as defined in the specification of the instant invention to the nucleic acid sequence of SEQ ID NO 2.

It would be remedial to recite that the isolated protein comprises or consists of the amino acid sequence of SEQ ID NO: 2.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite in the recitation of "hybridizes under stringent conditions" because the metes and bounds of the claimed conditions are ambiguous and are not specific. In turn, the metes and bounds of the claimed nucleotide sequences are not defined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3 and 32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants claim a genus of proteins encoded by nucleic acids that hybridize under stringent conditions with a nucleic acid comprising all or a part of the nucleotide sequence set forth in SEQ ID NO: 1. Applicants claim a genus of fusion proteins comprising an amino acid or a subsequence of SEQ ID NO: 2.

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus. In the instant case, applicants only disclose MutY, which amino acid sequence corresponds to SEQ ID NO: 2 and which nucleotide sequence corresponds to SEQ ID NO: 1. Applicant teaches that "stringent hybridization" refers to hybridizations or wash conditions under which nucleic acid will primarily hybridize to its target subsequence (page 25, line 23-27). The disclosure of these two sequences is not accompanied by a disclosure as to the relative properties of these sequences that are required for MutY function. Neither applicant nor the prior art provide a correlation between the structure of the recited sequences and their DNA repair activity. Given the diversity of

sequences that will hybridize to all or part of SEQ ID NO: 1, and the inability to determine which will also have the essential element, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

In the instant case, applicants only disclose SEQ ID NO:2 that has DNA repair activity. An amino acid sequence or subsequences or parts of SEQ ID NO: 2 are not disclosed that have DNA repair activity. Neither applicant nor the prior art provide a correlation between the structure of the recited sequences and their DNA repair activity. Given the diversity and large size of the genus of amino acids, subsequences or parts of SEQ ID NO: 2, and the inability to determine which will also have DNA repair activity, it is concluded that the invention must be empirically determined. In an unpredictable art, the disclosure of one species would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Conclusion

Claim 1-3 and 32 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for

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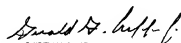
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the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maria B Marvich, PhD
Examiner
Art Unit 1636

September 22, 2003


GERRY LEFFERS
PRIMARY EXAMINER